

10/531433  
JC12 Rec'd PCT/PTC 15 APR 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: KUZ-0024

Inventors: Ito et al.

Serial No.: Not Yet Assigned

Filing Date: Herewith

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Title: Transdermal Patch for External Use  
Comprising Fentanyl

"Express Mail" Label No. EV626224545US

Date of Deposit April 15, 2005

I hereby certify that this paper is being deposited with the  
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By Kathleen A. Tyrrell  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R.  
§§1.97-1.98, information relating to the above-identified  
application is hereby disclosed. Inclusion of information in  
this statement is not to be construed as an admission that this  
information is material as that term is defined in 37 C.F.R.  
§1.56 (b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

( ) Certification in Accordance with §1.97(e) is attached hereto; or

( ) Authorization to charge Deposit Account No. 50-1619 the fee of \$180.00 as set forth in §1.17(p) is provided.

( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

(XX) References AA, BA, BB, BC, BD and BJ are in the English language. References BA, BB, BC, BD and BJ relate to references BE, BI, BG, BH and BK, respectively. English Abstracts are provided for References BF and BL.

Respectfully submitted,



Kathleen A. Tyrrell  
Registration No. 38,350

Date: April 15, 2005

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66 E. Main Street  
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|--|--|-------------------------|---|
| <p>Form PTO-1449 Modified<br/>List of Patents and Publications<br/>Cited by Applicant<br/>(Use several sheets if necessary)</p> <p>U.S. Department of Commerce</p> |  | Docket No.<br>KUZ-0024  | Serial No.<br>10/531433<br>Not Yet Assigned |
|  |  | Applicant<br>Ito et al. |   |
|  |  | Filing Date<br>Herewith | Group<br>Not Yet Assigned                   |

## U. S. PATENT DOCUMENTS

| Examiner Initial |    | Document No. | Date     | Name            | Class | Subclass |
|------------------|----|--------------|----------|-----------------|-------|----------|
| /M.Y./           | BA | 6,139,866    | 10-31-00 | Chono et al.    | 424   | 443      |
| /M.Y./           | BB | 4,588,580    | 5-13-86  | Gale et al.     | 424   | 21       |
| /M.Y./           | BC | 2003/0109819 | 6-12-03  | Tsuruda et al.  | 602   | 48       |
| /M.Y./           | BD | 5,770,221    | 6-23-98  | Nakamura et al. | 424   | 449      |
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|                  |    |              |          |                 |       |          |
|                  |    |              |          |                 |       |          |
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## FOREIGN PATENT DOCUMENTS

| Examiner Initial |    | Document No.   | Date     | Country | Translation YES              | NO |
|------------------|----|----------------|----------|---------|------------------------------|----|
| /M.Y./           | BE | 10-45570       | 2-10-98  | Japan   | Relates to BA                |    |
| /M.Y./           | BF | 04-095023      | 3-27-92  | Japan   | English Abstract             |    |
| /M.Y./           | BG | WO 01/43729 A1 | 6-21-01  | Japan   | English Abstract and Ref. BC |    |
| /M.Y./           | BH | WO 95/31190    | 11-23-95 | Japan   | English Abstract and Ref. BD |    |
| /M.Y./           | BI | 61-37725       | 2-22-86  | Japan   | English Abstract and Ref. BB |    |

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| EXAMINER | /Micah Paul Young/ (03/31/2008) | DATE CONSIDERED | 03/31/2008 |
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| <p><b>Form PTO-1449 Modified</b><br/> <b>List of Patents and Publications</b><br/> <b>Cited by Applicant</b><br/> <b>(Use several sheets if necessary)</b></p> <p>U. S. Department of Commerce</p> | <p>Docket No.</p>                         | <p>Serial No.</p>                                      |
|  | <p><b>KUZ-0024</b></p>                    | <p><b>10/53143B</b></p> <p><b>Not Yet Assigned</b></p> |
|  | <p>Applicant</p> <p><b>Ito et al.</b></p> |  |
|  | <p>Filing Date</p> <p><b>Herewith</b></p> | <p>Group</p> <p><b>Not Yet Assigned</b></p>            |

**U. S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

| Examiner Initial                | Document No.   | Date            | Country | Translation        |    |
|---------------------------------|----------------|-----------------|---------|--------------------|----|
|                                 |                |                 |         | YES                | NO |
| /M.Y./                          | BJ WO 91/16085 | 10-31-91        | PCT     | X                  |    |
| /M.Y./                          | BK 5-507682    | 11-5-93         | Japan   | Relates to Ref. BJ |    |
| /M.Y./                          | BL 2000-044476 | 2-15-00         | Japan   | English Abstract   |    |
|                                 |                |                 |         |                    |    |
|                                 |                |                 |         |                    |    |
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**EXAMINER**

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|---|--|-------------------------|--------------------------------|
| Form PTO-1449 Modified  |  | Docket No.<br>KUZ-0024  | Serial No.<br>Not Yet Assigned |
| List of Patents and Publications<br>Cited by Applicant<br>(Use several sheets if necessary) |  | Applicant<br>Ito et al. |                                |
| U.S. Department of Commerce   |  | Filing Date<br>Herewith | Group<br>Not Yet Assigned      |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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|--------|----|--|
| /M.Y./ | AA | Roy et al., "Controlled Transdermal Delivery of Fentanyl:Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design", Journal of Pharmaceutical Sciences 1996 85(5):491-495 |
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